**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

# APPLICATION FOR LICENSE FOR THE MANUFACTURE OF ALLERGENIC PRODUCTS

*Form Approved: OMB No. 0910-0124.*
*Expiration Date: November 31, 2001.*
*See Page 5 For OMB Statement.*

DATE SUBMITTED

**NOTE:** This report is mandated by Section 351 of the Public Health Service Act, the Federal Food, Drug and Cosmetic Act, Section 502 and Title 21 CFR Part 600. No license may be granted unless this completed application form has been received.

## GENERAL INSTRUCTIONS

Type or print legibly in ink. Complete all items. Items which are not applicable enter "NA". If more space is needed for any item, continue on an 8 1/2 X 11 sheet, reference the entry by item number, and attach. Allow 1 inch top margin for filing purposes. Submit the original and yellow copy of the completed application. Assemble and staple each set, including all attachments. The application forms must be dated and signed by the responsible head. Return the application to DHHS/PHS, FDA/Director, Center for Biologics Evaluation and Research (HFM-370), 1401 Rockville Pike, Rockville, MD 20852-1448.

## I. GENERAL INFORMATION

1. NAME OF THE FINAL PRODUCT FOR WHICH APPLICATION FOR LICENSE IS BEING MADE

***Check One:***
☐ NEW APPLICATION
☐ REVISED APPLICATION

2. NAME, ADDRESS, AND ZIP CODE OF MANUFACTURER

TELEPHONE NO. *(Include area code)*

3. COMPLETE ADDRESS(ES) OF LOCATION(S) WHERE PRODUCT IS MANUFACTURED

## II. SOURCE MATERIALS

4. NAME AND ADDRESS OF EACH SUPPLIER OF SOURCE MATERIAL, e.g., POLLEN, FOOD, MOLDS, ETC.

5. a. LICENSED MANUFACTURER INSPECTS SUPPLIER(S) OF SOURCE MATERIALS? ☐ YES ☐ NO
b. RECORDS MAINTAINED? ☐ YES ☐ NO

6. DESCRIBE METHOD OF OBTAINING SOURCE MATERIAL, INCLUDING THE PROPAGATION OF MOLDS, IF APPLICABLE

7. a. HOW IS PURITY AND IDENTITY OF SOURCE MATERIAL ESTABLISHED?

b. IS A WRITTEN CERTIFICATION RECEIVED FROM SUPPLIER OF EACH SHIPMENT OF SOURCE MATERIAL? ☐ YES ☐ NO

**III. EXTRACTION AND PREPARATION OF FINAL PRODUCT**

8. DESCRIBE TREATMENT AFTER RECEIPT AND PRIOR TO EXTRACTING THE SOURCE MATERIALS, AND CONDITIONS UNDER WHICH THE MATERIAL IS STORED.

9. METHOD OF EXTRACTION IN DETAIL, INCLUDING AT WHAT TEMPERATURE AND TIME REQUIRED FOR EXTRACTION

10. HOW IS EXTRACT STANDARDIZED?

**IV. PRESERVATIVE**

| 11. KIND | AMOUNT | WHEN ADDED | ACCEPTABLE RANGE THROUGHOUT DATING PERIOD |
|---|---|---|---|
| | | | |

12. IN WHAT STRENGTHS AND FORMS IS THE PRODUCT MARKETED?

13. DESCRIBE PREPARATION OF FINAL PRODUCT. INCLUDE DESCRIPTION OF ANY DILUENTS USED AND THE STERILE FILTRATION PROCEDURE

14. HOW ARE THE CONTAINERS AND STOPPERS TREATED AND STERILIZED? INCLUDE WRITTEN SPECIFICATIONS FOR CONTAINERS AND CLOSURES

15. HOW ARE THE CONTAINERS FILLED? AND UNDER WHAT PRECAUTIONS? INCLUDE INFORMATION ON SIZE AND TYPE OF ANY FILTERS USED. DESCRIBE HOW FILLING PROCEDURE IS VALIDATED

**V. LABORATORY TESTING**

16. DESCRIBE STERILITY TESTS *(bulk or stock concentrate and final containers)*

17. DESCRIBE GENERAL SAFETY TEST

18. DESCRIBE POTENCY TESTS PERFORMED

19. DESCRIBE IDENTITY TEST USED

20. WHAT OTHER TESTS ARE MADE? DESCRIBE IN DETAIL, INCLUDING IF TEST IS PERFORMED ON BULK OR FINAL CONTAINER

21. a. HOW IS THE DATE OF MANUFACTURE OF PRODUCT ESTABLISHED?

b. WHAT IS THE EXPIRATION DATE OF THE PRODUCT AND HOW IS IT CALCULATED?

22. HOW IS THE PRODUCT FOR MARKETING STORED AND AT WHAT TEMPERATURE:

23. a. WHEN IS THE DATE PLACED ON THE FINAL CONTAINERS?

b. IF FINAL PRODUCT IS FREEZE-DRIED, WHAT EXPIRATION DATE IS ASSIGNED TO THE RECONSTITUTED PRODUCT?

24. ADDITIONAL INFORMATION AND MATERIALS TO BE SUBMITTED OR THE COMPETE FILING OF APPLICATION *(State if attached or submitted separately)*

a. Examples of all records used in manufacturing and testing of a representative lot of the product submitted in support of license application.

b. Printer's proofs of all labels, including the direction circular, together with a prototype of a complete "mock-up" package. Use "Transmittal of Labels and Circulars," Form FDA 2567.

c. Samples of protocols of manufacturer's tests of the product, including identification of the stage(s) of manufacture represented by the sample(s) submitted.

d. Clinical evidence of safety, potency, and effectiveness of the product, including summaries of results from all pertinent studies contained in IND filing.

e. Stability data to assure the safety, purity and potency of the final product throughout the requested dating period.

f. Environmental impact analysis report as required by 21 CFR, Part 601.2.

25. COMMENTS

26. **NAMES AND TITLES OF EXPERTS RESPONSIBLE FOR THE PRODUCTION AND TESTING OF PRODUCT**

| TITLE | TYPED NAME | SIGNATURE |
|---|---|---|
| | | |
| | | |
| | | |

**CERTIFICATION**

I certify that all statements made in this application are true and correct to the best of my knowledge and ability. I am familiar with the pertinent Sections of Title 21, Code of Federal Regulations, and am aware of my responsibilities described therein. **WARNING:** A willfully false certification is a criminal offense. U.S. Code, Title 18, Section 1001.

| SIGNATURE OF RESPONSIBLE HEAD | TYPED NAME AND TITLE | DATE |
|---|---|---|
| | | |

**Paperwork Reduction Act Statement:**
A federal agency may not conduct or sponsor and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 12 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to:

DHHS/PHS/FDA/Director
Center for Biologic Evaluation and Research (0910-0124)
1401 Rockville Pike (HFM-370)
Rockville, MD 20852-1448